## REMARKS

Claims 1, 6 and 11 have been amended for clarity.

Claims 24-28 have been added as new. Support for these claims can be found in the specification, e.g., page 6 paragraph bridging page 7; page 8, lines 26-28 and page 9, lines 13-15.

As such, Claims 1-28 are pending after entry of new claims 24-28.

No new matter has been added. As such, Applicant respectfully requests entry thereof.

Applicant respectfully requests reconsideration of the application in view of the amendments and remarks made herein.

## REJECTION UNDER 35 U.S.C. §103

Claims 1-18 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Petrus (U.S. 6,399,093 B1) in view of Crandall (U.S. Patent Application Publication No. US 2002/0164389 A1) and Biederman et al (U.S. Patent No. 5,980,921). The Applicants respectfully submit that Claims 1-18 are patentable over the cited references.

The M.P.E.P. teaches at §1242 that:

> To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, whether in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must a reasonable expectation of success. **Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.**

Independent Claims 1 and 11, and the claims that depend therefrom, recite methods for at least ameliorating a symptom associated with the carpal tunnel that include topically applying an effective amount of a topical NSAID formulation to a palmar dermal surface proximal to the carpal tunnel (Claim 1) and a method for treating a human suffering from pain caused by pressure on the median nerve that includes topically applying a nonsalicylate NSAID formulation to the palmar dermis proximal to the median nerve (Claim 11). As such, in order to qualify as a proper reference under 35 U.S.C. §102(e), the reference or combination of references must disclose all the claimed limitations and each must have a filing date prior to that of the present application, which filing date is December 26, 2001.

The Petrus patent teaches a method and composition for the treatment of musculoskeletal disorders by application of a topical compositions. However, the only mention of carpal tunnel is a mention in the background section of Petrus that describes that occupational injury may result in musculoskeletal injuries and notes carpal tunnel syndrome as an occupational hazard (abstract, col. 1, lines 27-43). Petrus also teaches that a component of the inventive composition may include NSAIDs (col. 4). However, Petrus does not teach or even suggest topically applying an effective amount of a topical NSAID formulation to a palmar dermal surface proximal to the carpal tunnel to treat a symptom associated with pressure applied to the median nerve (Claim 1) or topically applying a nonsalicylate NSAID formulation to the palmar dermis proximal to the median nerve to treat a human suffering from pain cause by pressure on the median nerve (Claim 11).

The Examiner relies on Crandall to make up for the deficiencies of Petrus. Specifically, the Examiner notes that "The Crandall publication discloses methods for the treatment of carpal tunnel syndrome (See Abstract). Treatment is effected, in one embodiment, by the use of a topical formulation, applied to the wrist of a subject in need of treatment (See Sections [0034] and [0046]). Suitable dosage forms for topical applications include creams and pads (See Claim 1, 2 and 4)."

The Applicants respectfully submit that the Crandall publication is not a proper reference under 35 U.S.C. §103(a) in this regard because the filing date of the relevant subject matter in Crandall relied upon by the Examiner in this rejection is after the filing date of the present application.

The filing date of the Crandall publication is April 19, 2002 and the publication date is November 7, 2002, which dates are after the filing date of the subject application. The Examiner seems to rely on the priority date of the Crandall publication to make this rejection. The Crandall publication is a continuation-in-part application of U.S. Patent No. 6,306,383 (the '383 patent) filed on September 19, 1999 which is a continuation of U.S. provisional applications Ser. Nos. 60/100,530, 60/114,813 and 60/123,594 filed on Sep. 16, 1998, Jan. 6, 1999 and Mar. 10, 1999, respectively. The Applicants respectfully submit that relevant subject matter relied upon by the Examiner in making this rejection was not disclosed in the parent of the Crandall publication and thus the relevant matter relied upon in making this

rejection carries the filing date of April 19, 2002- a date after the filing date of the subject application as noted above.

The M.P.E.P. at §2136.03 states that "[i]n order to carry back the 35 U.C.C. 102(e) critical date of the U.S. patent reference to the filing date of a parent application, the parent application must ...support the invention claimed as required by 35 U.S.C. 112, first paragraph."

The matter described in the Crandall publication cited by the Examiner in making this rejection is not taught in the '383 patent at all, nor is any analogous matter taught. The '383 patent is directed towards a method for topical treatment of scars with protein kinase C ("PKC) inhibitors and a penetrating agent for inhibiting PKC activity in the skin, muco-cutaneous junction and underlying structures and disease processes relates to it (see, e.g., the Abstract and Summary of the Invention). In fact, the only mention of carpal tunnel at all in the '383 patent is the note that such processes may include "carpal tunnel disease 2$^{nd}$ to fibrosis" (col. 2, lines 13-17). There is no teaching of treating carpal tunnel syndrome by the use of a topical formulation applied to the wrist as "wrist" is not even mentioned at all in the '383 patent and specifically the passages cited by the Examiner relating to application of a topical formulation to a wrist of a subject to treat carpal tunnel syndrome (Sections [0034] and [0046]) are not described in the '383 patent. Accordingly, relevant matter relied on by the Examiner to make this rejection, i.e., matter related to treatment of carpal tunnel syndrome by the use of a topical formulation applied to the wrist of a subject in need of treatment, was new matter in the Crandall publication and was not described in the '383 patent. As such, this matter carries the filing date of the Crandall publication which is after the date of the subject application. Accordingly, the filing date of the '383 parent or any priority date thereof can not be used as the 35 U.S.C. 102(e) critical date for the relevant matter used in making this rejection because it does not support the relevant claims of the Crandall publication as required by 35 U.S.C. 112, first paragraph.

As such, the filing date to be used for the purposes of 35 U.S.C. 102(e) is the date the relevant matter was disclosed in the Crandall publication, namely April 19, 2002, which is not a date prior to the filing date of the present application. Accordingly, because the filing date of the relevant matter for the purposes of 35 U.S.C. 102(e) of the Crandall publication is

after the filing date of the subject application, the Crandall publication cannot be used as a reference under 35 U.S.C. §102(e) in making this rejection.

The Examiner cites Biedermann et al. "merely as a teaching reference to point out that diclofenac and indomethacin are known in the art as acetic acid derivatives". However, Biedermann et al. fail to make up for the deficiencies of Petrus for at least the reason that Biedermann et al. fail to teach or suggest does not teach or even suggest topically applying an effective amount of a topical NSAID formulation to a palmar dermal surface proximal to the carpal tunnel to treat a symptom associated with pressure applied to the median nerve or topically applying a nonsalicylate NSAID formulation to the palmar dermis proximal to the median nerve to treat a human suffering from pain cause by pressure on the median nerve as Biedermann et al. is directed towards regulating the oily/shiny appearance of skin and in fact specifically teach application to the scalp (see e.g., col. 17, lines 13-17; Examples 5 and 6) and the face (see e.g., col. 2, lines 42-44 and lines 59-61 and Examples 1, 2, 3, and 4).

Accordingly, for at least the reasons described above, the Applicants respectfully submit that a proper *prima facie* case of obviousness cannot be sustained. As such, the Applicants respectfully request that this rejection be withdrawn.

Claims 19-23 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Petrus (U.S. 6,399,093 B1) in view of Crandall (U.S. Patent Application Publication No. US 2002/0164389 A1), Biederman et al (U.S. Patent No. 5,980,921) and Shudo et al. (U.S. Patent Publication No. US 2002/0176886). The Applicants respectfully submit that Claims 19-23 are patentable over the cited references for at least reasons analogous to those described above.

Specifically, Claim 19 and the claims that depend therefrom, specify a kit that includes instructions for practicing the method according to Claim 1. However, as described above Petrus fails to teach or suggest the method of Claim 1, the relevant teaching of Crandall does not qualify as prior art to this application, and Biedermann et al., fail to make up for the deficiencies of Petrus. Furthermore, as Shudo et al. is cited solely for disclosing kits, Shudo et al. also fail to make up for the deficiencies of Petrus. Accordingly, the cited references either alone or in combination fail to teach or suggest a method according to Claim

1 and thus fail to teach or suggest a kit that includes instructions for practicing a method according to Claim 1. Therefore, the Applicants respectfully request that this rejection be withdrawn.

## CONCLUSION

In view of the above amendments and remarks, this application is considered to be in good and proper form for allowance and the Examiner is respectfully requested to pass this application to issue.

If, in the opinion of the Examiner, a telephonic interview would expedite prosecution of this application, the Examiner is invited to contact the undersigned at (650) 833-7770.

If the Patent Office determines that fees, including extensions of time, are required, the Applicants hereby petition for any required relief, including extensions of time, and authorize the Commissioner to charge the cost of such to our Deposit Account No. 50-0815, Order No. CALD005.

Respectfully Submitted,

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